



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0144; FRL-9979-59]

TSCA Chemical Substances; Unique Identifier Assignment and Application Policy;

Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: As amended in 2016, the Toxic Substances Control Act (TSCA) requires EPA to develop a system to assign a unique identifier (UID) whenever it approves a confidential business information (CBI) claim for the specific chemical identity of a chemical substance, to apply this UID to other information concerning the same chemical substance, and to ensure that any non-confidential information received by the Agency identifies the chemical substance using the UID while the specific chemical identity of the chemical substance is protected from disclosure. EPA previously requested comment on several approaches for assigning and applying UIDs. EPA has determined that it will use a numerical identifier that incorporates the year the CBI claim was asserted, and will apply this UID to non-confidential information related to the chemical substance, except where the Agency's act of applying the UID would itself disclose to the public the confidential specific chemical identity that the UID was assigned to protect.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you have submitted or expect to submit information to EPA under TSCA. Persons who would use UIDs assigned by the Agency to seek information may also be affected by this action. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Manufacturers, importers, or processors of chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

B. How Can I Get Copies of this Document and Other Related Information?

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0144, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket

available at <http://www.epa.gov/dockets>.

II. Background

A. What is the Authority for this Action?

The June 22, 2016, amendments to TSCA by the Frank R. Lautenberg Chemical Safety for the 21st Century Act added a requirement in TSCA section 14(g)(4) for EPA to, among other things, “assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure.” EPA is required to use the “unique identifier assigned under this paragraph to protect the specific chemical identity in information that the Administrator has made public” and to “apply that identifier consistently to all information relevant to the applicable chemical substance,” including “any non-confidential information received by the Administrator with respect to a chemical substance . . . while the specific chemical identity of the chemical substance is protected from disclosure.” 15 U.S.C. 2613(g)(4).

B. EPA Sought Public Comment

The requirements to assign a UID and the unreconciled requirements concerning application of the UID and protection of CBI are more fully discussed in a document that published in the **Federal Register** on May 8, 2017. (See 82 FR 21386; May 8, 2017; hereafter “May 2017 **Federal Register** document”.) EPA noted drawbacks to each of the two alternative approaches discussed in the May 2017 **Federal Register** document, and subsequently developed a third alternative approach for reconciling the competing requirements of TSCA section 14(g), on which it requested comment in the **Federal Register** on February 8, 2018. (See 83 FR 5623; hereafter “February 2018 **Federal Register** document”).

III. Policy

A. *UIDs will be a Numerical Identifier*

The UID cannot be the specific chemical identity, or a structurally descriptive generic term. TSCA section 14(a)(4)(A)(i). Consequently, EPA has developed a system to assign UIDs for each substance for which it makes a final determination approving a CBI claim for specific chemical identity. The UID is a number that incorporates the year that the claim was asserted (e.g., the first approved claim asserted in 2019 would be UID-2019-00001).

Including this date will facilitate tracking of the expiration of the CBI claims for specific chemical identity made in that document, pursuant to TSCA section 14(e). The reasons for not using a preexisting identifier, such as the accession number, are further explained in the May 2017 **Federal Register** document. Note that in the May 2017 **Federal Register** document, it was suggested that the UID year would be based on year the claim was *approved*. See 82 FR at 21387. However, because the year of approval may be different from the year the claim was asserted (e.g., claims made in December may not be approved until the following February), and because the initial expiration date of the claim runs from the point that the claim was asserted, EPA determined that the date would better facilitate claim expiration tracking if it were based on the year the claim was *asserted*.

B. *EPA will Apply UIDs to Related Documents, Except Where It Discloses Confidential Chemical Identity*

EPA is adopting the “third alternative approach,” as described in the February 2018 **Federal Register** document. Under this approach, EPA will assign one UID per chemical substance. In most cases, EPA will apply the UID to all non-confidential information relevant to the applicable chemical substance, from any company. However, in a

small number of cases, EPA will not apply the UID to some non-confidential documents, in order to preserve approved, still-valid CBI claims for specific chemical identity. These would be cases in which the non-confidential document itself does not undermine the CBI claim, but EPA's application of the UID to that document would result in a linkage that would undermine the CBI claim and reveal the CBI. The criterion for application of the UID to submissions made by different submitters is that *the Agency's act of applying the UID must not disclose to the public the confidential specific chemical identity that the UID was assigned to protect.*

EPA believes that this is the best of the approaches considered because it most appropriately balances the two purposes of the UID provisions: to provide public linkages between related non-confidential information concerning a particular confidential chemical substance (i.e., to promote transparency), and to protect information that EPA has determined to be entitled to confidential treatment. It does so by providing linkages to the maximum extent possible while still preserving valid claims of CBI for chemical identity. The third alternative approach also has the advantage of being more straightforward to administer than the other two alternative approaches considered. Most public commenters supported this approach over the other alternatives for similar reasons.

By contrast, the other two alternative approaches (described more fully in the May 2017 **Federal Register** document) would not provide this balance, and would have other significant disadvantages. The "first alternative approach" would have construed section 14(g)(4)(C) as instructing EPA to ensure that any non-confidential information received by EPA concerning a confidential chemical substance should identify the substance using *only* the UID, for so long as the confidential identity remained protected from disclosure. This

approach would have involved carefully searching for and removing specific chemical identifying information from all documents relating to the applicable chemical, even where that information was not claimed as CBI, in order to replace that specific information with the UID. This approach would have provided a linkage between documents concerning the same chemical, while at least superficially maintaining the confidentiality of the CBI claim for chemical identity, but would require withholding or withdrawing information that would otherwise be (or was previously) public. Moreover, because many related documents may already have long been made public, removing chemical identities from these documents would have been ineffectual in some cases (such as when the older, complete version of a document can be compared with the newer version with specific chemical identity redacted).

In the “second alternative approach,” whereby a UID would be assigned to each chemical-company combination (different companies submitting information on the same substance would be assigned different UIDs for that substance), the CBI protection goal would at least initially be met, but only at considerable expense to the other goal of the UID provisions—to provide the public with links between related documents. In addition, this approach would have raised its own administrative issues, such as what to do with the UID in the case that a company or parts of a company changes ownership; how such UIDs would be applied to EPA-generated documents that are relevant to a substance that is referenced in multiple submissions from different companies; or how the multiple UIDs would be handled in the case that one company withdraws or permits its CBI claim to expire while the other does not. Finally, this approach seems unreconciled with the TSCA section 8(b)(7) requirement to publish UIDs alongside other identifiers for the same chemical—accession number, generic name, and PMN number, where applicable. Any list that includes all of this

information for each chemical would automatically link submissions from different companies by including all of the UIDs and/or by using the same accession number for multiple listings on the same chemical. (For example, if Chemical X has three UIDs, assigned to three different company claims, they would all be linked on this list, because Chemical X only has one accession number, and the list is supposed to include both accession number and UID.)

IV. Public Comments

A. Summary of Public Comments

In response to the two requests for comment, in the May 2017 and February 2018 **Federal Register** documents, EPA received a total of 20 comments from 14 identified commenters (some commenters responded to both requests).

In response to the first request for comment (May 2017 **Federal Register** document), most commenters, including seven of eight industry or trade group commenters, and one non-governmental organization (NGO) commenter, preferred the one UID per company-chemical combination approach (“second alternative approach”). No commenter supported the “first alternative approach.” One NGO commenter argued that assigning more than one UID to any given chemical was contrary to the purpose and requirements of the UID provisions. One trade association argued for an even more complex system of UIDs (the “parent-daughter identifier approach”), whereby even submissions from the *same* company may be assigned different UIDs, and would involve assigning additional UIDs for EPA-generated documents and other third-party submissions—none of which would be linkable by the public.

In response to the second request for comment (February 2018 **Federal Register**

document), most commenters expressed support for the “third alternative approach”—applying the UID to all related information, but with some exceptions to preserve approved and still-valid CBI claims for chemical identity, as explained above. Commenters supporting the third alternative approach included three trade groups that had previously supported the one UID per company-chemical combination approach, and two more trade groups that had not previously commented. One NGO commenter maintained the position that they had taken in their earlier comment, in response to the first request for comment, that EPA should apply the UID to all related documents, regardless of the effect on approved CBI claims for chemical identity. This same commenter indicated, however, that the third alternative approach was an improvement over, and would be preferred to, the other two alternatives. One trade group maintained its preference for a “parent-daughter identifier” approach. Two commenters did not express a preference or position with respect to approach, but requested clarification regarding EPA’s CBI review procedures or commented in general support of balancing public transparency with CBI protections.

B. Response to Comments

EPA has prepared a separate response to comments document, a copy of which is available in the docket for this action (Ref. 1), and is also including the following summary response to selected comments.

1. *“Parent-daughter identifier” approach.* One commenter proposed that EPA adopt a system of document identifiers, such that documents concerning the same substance would use several different identifiers, the relationship between which only EPA would be aware. Documents concerning the same substance, submitted by different companies, and even documents submitted by the same company, would or could have different identifiers.

The public would be able to link together only those documents that are submitted by the same person, and that have the same CBI status (CBI vs. non-CBI). The commenter explained that this system would provide more protection to CBI information than would be provided by using one chemical identity per company, as in the second alternative approach.

This approach would be largely inconsistent with both the letter of TSCA section 14(g)(4) and the intent of setting up a UID system. EPA interprets TSCA section 14(g)(4)(A)(i) (requiring the Agency to “assign a unique identifier to *each* specific chemical identity” (emphasis added)), to indicate that the UID was intended to be a single identifier for each chemical. Moreover, as noted in the February 2018 Federal Register document, the reason for assigning multiple UIDs per chemical (CBI protection) is not possible to reconcile with the TSCA section 8(b)(7) requirement that for each confidential chemical substance, EPA “shall make available to the public . . . the unique identifier assigned under [section 14], accession number, generic name, and, if applicable, premanufacture notice case number.” The publication of the UIDs alongside their corresponding accession number (for which there is generally only one per chemical) would cause all of the UIDs for a given substance to be linked together. The approach advocated in this comment would also largely defeat one of the two purposes of the UID provision—to provide a publicly-accessible link between information concerning the same substance.

2. *“Straightforward” approach.* One commenter asserted that the text of section 14(g)(4) is plain about EPA’s obligations to apply the UID uniformly, regardless of consequence for approved CBI claims, and thus advocated for a reading of the statute where one UID is assigned to each chemical, and making no exceptions in applying UIDs to related information (i.e., the “straightforward” approach). EPA disagrees that Congress plainly

intended that approved, valid CBI claims should be disregarded as UIDs are applied to related documents. As is noted in the May 2017 Federal Register document, EPA understands the UID as having two purposes: providing a public linkage between information on the same chemical substance, and protecting approved CBI claims for specific chemical identity. Under the “straightforward” approach, those two purposes would conflict with each other in certain circumstances, while the third alternative approach selected by EPA balances the two purposes without this conflict.

The UID is specifically described in the statute as an identifier assigned “to protect the specific chemical identity” of the subject chemical. Section 14(g)(4)(D). It would plainly undermine that Congressional purpose if application of the UID itself were the means by which an otherwise valid chemical identity CBI claim was disclosed. Congress’ intention that the UID preserve valid CBI claims is further evidenced by the requirement that the UID “shall not be . . . the specific chemical identity.” Section 14(g)(4)(A)(i). Similarly, section 14(g)(4)(B) requires EPA to publish an annual list of confidential chemical substances “referred to by their unique identifiers . . . including the expiration date for each such claim.” This further reflects Congress’ understanding that the duration of a valid CBI claim would be determined by its expiration date and that the UID would serve to link documents pertaining to a confidential chemical during that period, not to terminate the period. Section 14(g)(4)(C) in turn instructs EPA to ensure that any non-confidential information received by EPA regarding a chemical substance “on the list published under paragraph (B)” while the specific identity is protected from disclosure identifies the chemical using the UID. It is apparent that Congress intended the UID to serve the function of enabling the public to link such non-confidential information to other documents pertaining to the same confidential

chemical during the life of the valid CBI claim as reflected on the list under paragraph (B), not to terminate the period of protection. Finally, section 14(g)(4)(D) requires EPA to link the specific identity of a chemical substance to the corresponding UID in three circumstances: where the claim has been denied, has expired, or has been withdrawn. If Congress had intended for the application of the UID itself to reveal the confidential chemical identity, it presumably would have included this circumstance in the list in section 14(g)(4)(D).

The approach suggested by the commenter might also tend to increase CBI claims for chemical identity. Many TSCA section 8(e) filings, for example, concern chemicals that are in the research and development (R&D) stage. At this early stage, not all companies claim the chemical identity as CBI. Under the “straightforward” approach, any time a company chooses to not claim an R&D chemical identity as CBI, they would foreclose any chance (of theirs, or of a competitor’s) to maintain a successful CBI claim for the specific identity of that substance in the future. This is because even if such a claim were made and approved in, for example, a section 5 Notice of Commencement, the confidential chemical identity, and the fact the substance is in commerce in the United States, would be revealed as soon as EPA applied the UID to the related R&D 8(e) submission and made the labeled submission public. In order to avoid this foreclosure of opportunity, TSCA section 8(e) submitters may feel compelled to claim more R&D chemical identities as CBI.

EPA believes that section 14(g)(4) is best read as instructing EPA to provide a public linkage of non-confidential information that concerns each confidential chemical substance, while simultaneously protecting approved and valid CBI claims. It is both appropriate and lawful for EPA to interpret conflicting requirements of a provision in a manner that

minimizes those conflicts, because provisions of a text should be interpreted in a way that renders them compatible and not contradictory. Accordingly, EPA is acting consistent with TSCA by attempting to balance two requirements that occasionally conflict with one another.

3. *UID application procedure.* Several commenters urged EPA to develop procedures to assure that confidential chemical identities are not inappropriately disclosed as EPA applies UIDs to related non-confidential documents. Some commenters also requested clarification on how exceptions to UID application will occur.

EPA has developed procedures for applying UIDs to related documents, prior to releasing those labeled documents to the public. EPA will search its records and screen incoming submissions for non-confidential information that relates to the applicable confidential chemical identity (using CASRN, accession number, PMN number, specific name, and/or other identifiers). These documents would be reviewed for relevance (i.e., to ensure that they are not mislabeled with the wrong CASRN or PMN number), then searched for mention of the confidential specific chemical identity that is protected by the UID (e.g., CASRN and/or specific chemical name).

Any relevant documents that do not reveal the confidential specific chemical identity in the public version would be labeled with the UID. Any relevant documents that mention this confidential specific chemical identity in the public version would be set aside for additional screening. EPA anticipates that documents in the latter category will be fairly rare. Documents subject to additional screening would be examined for information indicating that the confidential TSCA Inventory status may no longer be warranted (e.g., if the document reveals to the public that the chemical substance is offered for commercial distribution in the United States for TSCA uses). If there is no such public information

undermining the approved CBI claim, then the UID would not be applied to this document. The document would continue to be available to the public, and continue to include reference to the confidential chemical identity, but it would not be labeled with the UID.

If the result of the additional screening is that the chemical identity CBI claim appears no longer valid (i.e., EPA develops a reasonable basis to believe that the information no longer qualifies for protection from disclosure) or appears to have been withdrawn (for example, where a subsequent submission by the original claimant does not claim the specific chemical identity as CBI), EPA will proceed in accordance with section 14(f)(2)(B) and/or 14(e)(1)(B)(ii), as appropriate. Consistent with section 14(g)(4)(D), whenever a claim for protection of a specific chemical identity for which a UID has been assigned is subsequently denied by EPA, is withdrawn by the claimant, or expires, EPA will, to the extent practicable, clearly link the specific chemical identity to the UID in information that EPA has made public.

V. Annual UID List

Under TSCA section 14(g)(4)(B), EPA is required to “annually publish and update a list of chemical substances, referred to by their unique identifiers, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim.” EPA will be using the approach announced in this document and anticipates publishing the first annual list on EPA’s internet site in November of 2018.

VI. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket,

even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. 2018. Response to Comment Document for Unique Identifier Assignment and Application Policy.

Authority: 15 U.S.C. 2613.

Dated: June 21, 2018.

E. Scott Pruitt,

Administrator,

Environmental Protection Agency.

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